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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,264	12/08/2004	Andrea Mahn	4121-168	9836

23448 7590 04/10/2007  
INTELLECTUAL PROPERTY / TECHNOLOGY LAW  
PO BOX 14329  
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER
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WORLEY, CATHY KINGDON

ART UNIT	PAPER NUMBER
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1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/500,264

Applicant(s)

MAHN ET AL.

Examiner

Cathy K. Worley

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. The text of those sections of Title 35, U.S.Code not included in this action can be found in a prior Office action.

#### *Status of Claims*

2. Claims 1-19 have been cancelled. Claims 20-30 are pending and are examined herein.

#### *Objections and Rejections that are Withdrawn*

3. The objections to the specification for a title and abstract that were not sufficiently descriptive are withdrawn in light of the Applicant's amendments.

4. The rejection of claim 15 under 35 USC 112, second paragraph, is withdrawn in light of the Applicant's cancellation of the claim.

5. The rejections of claims 1, 4, 9-11, 13, and 15 under 35 USC 112, first paragraph for lack of written description and enablement are withdrawn in light of the Applicant's cancellation of the claims.

6. The rejection of claims 1, 4, 9-11, 13, and 15 under 35 U.S.C. 102(b) as being anticipated by Hausler et al. is withdrawn in light of the Applicant's cancellation of the claims.

7. The rejection of claims 1, 4, 9-11, 13, and 15 under 35 U.S.C. 102(b) as being anticipated by Tjaden et al. is withdrawn in light of the Applicant's cancellation of the claims.

*Claim Rejections - 35 USC § 112*

8. Claims 20-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in this rejection.

Claims 20 and 27 are indefinite because they lack agreement between the preamble of the methods and the positive method steps. Methods must be circular; the final step must generate the item the method is intended to produce. The method of increasing the content of one or more transgene-coded proteins or peptides in claims 20 and 27 ends in "one or more further desired transgenes", when it should end in - - ; wherein the content of the transgene-coded protein or peptide in said transgenic plant is increased relative to the content of the transgene-coded protein or peptide in a control plant of the same genetic background - - for claim 20; and - - ; wherein the content of the transgene-coded protein or peptide in said transgenic potato plant is increased relative to the content of the transgene-coded protein or peptide in a control plant of the same genetic background - - for claim 27.

9. Claims 20-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for increasing the concentration of a transgene-coded protein in a potato plant comprising transforming a potato plant with an antisense construct comprising a potato cDNA for an ATP/ADP transporter operably linked in antisense orientation to a promoter that functions in potato

plants, does not reasonably provide enablement for any other method of increasing the content of a transgene-coded biomolecule in any other species of plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to a method of increasing the content of one or more transgene-coded proteins or peptides in any type of plant by utilizing antisense inhibition of the endogenous plastidial ATP/ADP transporter gene.

The nature of the invention is a molecular biological approach utilizing antisense to suppress the expression of the endogenous ATP/ADP transporter in the chloroplasts of potatoes. This suppression results in an increase in accumulation of a transgene-encoded protein.

The prior art teaches that antisense constructs have been successful in suppressing the expression of endogenous ATP/ADP transporters in transgenic potatoes and tobacco (see Tjaden et al. (1998) *The Plant Journal*, Vol. 16, pp. 531-540 and Hausler et al. (1998) *Planta*, Vol. 204, pp. 366-376).

The Applicants teach how to make an antisense construct comprising a cDNA from potato and how to transform a potato plant with this construct and provides this as a working example (see pages 14-15).

However, the instant specification does not provide any further guidance for any host plant other than a potato plant.

There is a high degree of unpredictability regarding which species of plants will produce the desired result (an increase in protein or polypeptide) in response to antisense inhibition of the endogenous plastidiary ATP/ADP transporters. For example, Reiser et al. teach that *Arabidopsis* plants that are either knocked out for the endogenous transporter or, alternatively, have RNAi inhibition of the transporter had a reduced protein content rather than an increase in protein content (see Reiser et al. (2004) *Plant Phys.* Vol. 136, pp. 3525-3536, especially page 3532, Figure 11, panel C). Reiser et al teach that seed protein levels are decreased in seeds of these plants (see page 3531, left column, second paragraph). In Fig 10A, the plants lacking the plastidiary ATP/ADP transporter had a smaller size in short-day conditions, and in Fig 10B were certainly not bigger in long-day conditions [RNAi lines were similar physiologically to null lines (page 3528, right column,

paragraph 1]. Thus, there does not appear to be an increase in proteins in a plant lacking ATP/ADP transporters compared to the amount of protein in a wild-type plant. This demonstrates the unpredictability of inhibiting expression of a plastidiary ATP/ADP transporter in different species of plants to increase the amount of protein or peptide made in the plant.

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of skill in the art to determine which species of plants will produce an increased level of protein when the expression of the plastidiary ATP/ADP transporter is inhibited by antisense suppression.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the method of the claimed invention, and therefore, the invention is not enabled throughout the broad scope of the claims.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CKW



ANNE KUBELIK, PH.D.  
PRIMARY EXAMINER